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FOCUS ON TOBACCO REGULATION AND THE PUBLIC’S HEALTH

It has been over fifty years since the tobacco industry faced its first lawsuit by a lung cancer victim alleging negligence and breach of warranty (see *Pritchard v. Liggett & Myers Tobacco Co.*)¹ and over forty years since the Surgeon General released his report concluding that smoking causes lung cancer. Despite this passage of time, tobacco remains one of the “least-regulated consumer products in the marketplace,”² millions of Americans continue to smoke, teenagers continue to “join the army of the addicted in disturbingly large numbers,”³ and tobacco products still claim the lives of hundreds of thousands of Americans each year. While the initial efforts to control and regulate tobacco were at the federal level, the public health battle against tobacco products is now being fought on four levels of government: federal, state, local and international.

In the 1960s, the primary efforts aimed at regulating tobacco products were a result of Congressional and federal agency actions. After the Surgeon General’s Report in 1964, Congress passed the Federal Cigarette Labeling and Advertising Act in 1965 requiring warnings on all cigarette packs. Just two years later, in 1967, the FCC, after litigation on the issue, applied the “fairness doctrine” to cigarette advertisements requiring broadcasters to balance cigarette ads with antismoking advertisements. Three years after that, via passage of the Public Health Cigarette Smoking Act, Congress banned all cigarette ads on radio and television.

There was little regulatory action at any level during the 1970s, with the exception of a rule promulgated by the Civil Aeronautics Board in 1973 that airlines must create nonsmoking sections.

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FROM THE DIRECTOR

The University of Maryland’s Law & Health Care Program has been part of efforts to address the harmful effects of tobacco consumption. In 2001, the Program, in conjunction with the School’s Environmental Law Program, was instrumental in establishing the Legal Resource Center for Tobacco Regulation, Litigation and Advocacy at the University of Maryland School of Law. The Center has been involved in tobacco regulation initiatives at the local, state, national, and most recently, international level. In this issue, we celebrate the Center’s Fifth Anniversary and provide you with an update on what the Center has accomplished over its first five years as well as its plans for the future.

Diane Hoffmann, JD, MS

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Focus on Tobacco Regulation

Cont. from p. 1

The 1980s were a much more active time for tobacco regulation. State and local governments began to regulate smoking in public places but also passed laws protecting smokers from non-discrimination. At the federal level, in 1984, Congress passed the Comprehensive Smoking Education Act strengthening warnings on cigarette packages and ads, and in 1986, the Surgeon General issued his report on the harms associated with secondhand smoke.

The decade of the nineties brought several new approaches to tobacco regulation at the state and federal levels.

Following the passage by California citizens in 1988 of Proposition 99, a few states approved increases in cigarette taxes. In addition, the EPA designated environmental tobacco smoke (secondhand smoke) as a Class A carcinogen and proposed regulation of indoor air quality; the FDA proposed

jurisdiction over marketing of cigarettes and announced regulations aimed at restricting youth access to tobacco products; and states across the country filed suits against the tobacco industry to recover Medicaid costs associated with the treatment of patients for smoking related illness. While the FDA was not successful in its bid to regulate tobacco as an addictive drug, the EPA, after a law suit by the tobacco industry, was successful in its efforts to regulate secondhand smoke. Moreover, the Attorneys General of 46 states and 6 U.S. territories signed a \$206 billion Master Settlement Agreement (MSA) with the five largest tobacco manufacturers (Brown & Williamson, Lorillard, Philip Morris, R.J. Reynolds, Commonwealth Tobacco, and Liggett & Myers). Four states had previously settled with tobacco manufacturers for \$40 billion.⁴ The MSA ended a "four-year legal battle between the states and the industry that began in

1994 when Mississippi became the first state to file suit."⁵

The MSA settled all antitrust, consumer protection, common law negligence, statutory, common law and equitable claims for monetary, restitutionary, and injunctive relief alleged by each of the settling states for violations of the law that occurred in the year of payment or earlier. Under the provisions of the agreement, companies are exempt from future liability from state governments for tobacco-related Medicaid expenditures in

exchange for a combination of yearly settlement payments to the states and voluntary restrictions on advertising and marketing of tobacco products.⁶

During the 2000s, the effort to regulate tobacco has continued, primarily at the local and state levels and at the international level. States are taking a variety of tacks to reduce the deleterious effects of secondhand smoke and to reduce youth access to smoking. A number of states are using their portion of funds received under the



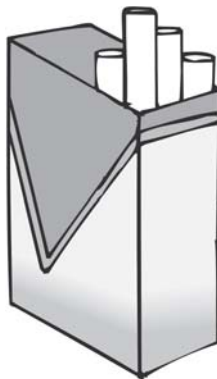
MSA to support antismoking programs, although some states have been criticized for spending the funds on totally unrelated activities.⁷ The trend to restrict smoking in public places has continued so that all 50 states and the District of Columbia now have laws or policies restricting smoking in certain places. These laws vary considerably from state to state with some simply requiring designated smoking areas in government buildings and others prohibiting smoking in virtually all public places and workplaces. Nineteen states, the District of Columbia, and Puerto Rico prohibit smoking in all workplaces, restaurants and bars.⁸ All 50 states and D.C. also now impose an excise tax on cigarettes, however these taxes range "from a high of \$2.575 per pack in New Jersey to a low of \$0.07 per pack in South Carolina."⁹ According to the American

Lung Association's web site on state legislation on tobacco issues, the national average for state cigarette excise taxes as of April 1, 2007 was \$1.02/pack.

All 50 states and the District of Columbia also prohibit the sale of tobacco products to minors. The laws vary in terms of how "minor" is defined and as to how the laws are enforced. Twenty-six states require minors who violate the youth access or smoking laws to perform community service in addition to, or in lieu of, a fine; nine states may suspend the driver's license of a minor who violates their youth access law; 16 states require minors to attend smoking education/cessation classes in addition to or instead of other penalties. In order to reduce youth access to tobacco products, 20 states also restrict customer access to cigarettes and other tobacco products and 14 of those states totally prohibit customers from having direct access to tobacco products and/or have language prohibiting the use of self-service displays. Many states also restrict the sale of tobacco products in vending machines.¹⁰

Newer areas of tobacco regulation at the state and local level include restrictions based on the harmful effects of secondhand smoke. While some states have made significant progress on banning smoking in public places, others still have much to do in this area. A cutting edge issue for states and local governments is regulation of smoking in private places, such as cars with children, foster homes, and residential places, e.g., condos and apartment buildings where individuals live in close quarters and smoke from one residential unit can drift to other units.

Another new area of tobacco regulation is legislation requiring that cigarettes sold in a state be fire resistant (or "fire safe"). Such legislation has



passed in at least ten states and is being considered in 19 states.¹¹

Regulation at the International Level

The newest frontier for tobacco regulation is at the global level. In May 2003, the member states of the World Health Organization agreed to the text of the Framework Convention on Tobacco Control (FCTC), the first public health treaty. Although the World Health Assembly unanimously approved the treaty, the fractious nature of negotiations leading up to approval of the treaty highlight the potential hurdles to successful implementation of treaty provisions. The treaty requires countries to "impose restrictions on tobacco advertising, sponsorship and promotion; establish new packaging and labeling of tobacco products; establish clean indoor air controls; and strengthen legislation to clamp down on tobacco smuggling."¹² There are currently 168 signatories to the treaty and 146 parties (member states who have signed and ratified it). The United

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THE CENTER FOR TOBACCO REGULATION, LITIGATION AND ADVOCACY—THE FIRST FIVE YEARS

In 2001, Maryland's General Assembly established the Cigarette Restitution Fund (CRF) which serves as the state's depository for all revenues received from the tobacco industry as a result of the Master Settlement Agreement (MSA). By law, the Cigarette Restitution Fund is used to fund the state's Tobacco Use Prevention and Cessation Program; the Cancer Prevention, Education, Screening, and Treatment Program; and other state programs that serve health, education, and tobacco prevention purposes. (As of January, 2003, Maryland ranked fifteenth among the 50 states and Washington, D.C. in its use of the settlement funds for tobacco-related health purposes.)

In 2001, in response to a proposal drafted by University of Maryland School of Law Professor Diane Hoffmann, the state, through the CRF,

provided the law school with funding to establish the Legal Resource Center for Tobacco Regulation, Litigation and Advocacy (the "Center"). The Center was created to provide expertise and resources for community groups, state and local legislatures and agencies, private entities, and lawyers attempting to reduce smoking and its related health impacts.

Getting Started

During the initial planning year for the Center (2001-2002), Michael Strande, a 2001 School of Law graduate (now Managing Director of the Center), met with the Health Officer and tobacco staff in each of Maryland's 24 local jurisdictions and with tobacco control advocacy groups throughout Maryland to determine the legal needs of the state's tobacco control community. The voluminous "Needs

Assessment" created by Strande served as the blueprint for the early operation of the Center. Initial activities of Center staff included meeting with local health department and community coalition members to hear about their local needs, drafting policies and legislation to meet those needs, assisting local governments obtain passage of local legislation, and keeping the statewide community informed about tobacco control policy work in Maryland and across the country with the publication of the bi-annual newsletter, *Tobacco Regulation Review*, and through the Center website, www.law.umaryland.edu/tobacco.

In 2002, Kathleen Dachille, a 1992 School of Law graduate, was recruited to join the School of Law faculty and to become the Center's Director. One of

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Dachille's first task was to start the Tobacco Control Clinic, a part of the law school's clinical offerings providing hands-on training to law students interested in public health policy development and implementation. Through the clinic, which typically enrolls ten students each year who work on Center related projects, the Center was able to expand its ability to serve the tobacco control community.

The Center has made significant inroads into tobacco control efforts during the first five years of its operations. Since its inauguration, Center staff has

provided litigation support to the County Attorney's Office in successfully defending the case. The Center also provided legal assistance to other jurisdictions in gaining passage of local tobacco control laws, including a Howard County prohibition against giving away cigarettes and a Prince George's County law requiring that cigarettes be sold only in packages of 20 or more. In addition, the Center helped several local jurisdictions including Carroll, Frederick, Garrett, Harford, and Kent Counties enforce a state law prohibiting the sale of tobacco to minors.



*Tobacco Center Staff (l-r):
Megan McDonald, Michael Strande, Kathleen
Dachille, Erin Smith, Jacqueline McNamara*

worked on many projects, big and small, at the national, state, and local levels. This year, the Center added international tobacco policy work to its agenda (see article, p. 7).

Tobacco Center: Work at the Local and State Levels

At the local level, the Center has provided advice to several counties considering the passage of clean indoor air legislation prohibiting smoking in restaurants and bars, areas left open by the state smokefree workplace regulations. After passage, one County's law (Montgomery County) was subsequently challenged in court, and the

same year, the Center drafted and helped usher through the General Assembly a law requiring that tobacco products sold in Carroll and Garrett Counties be placed behind the counter, out of the customer's reach.

Significant effort on the part of the Center toward the passage of the Maryland Clean Indoor Air Act paid off this year. The bill, which prohibits smoking in all public places and workplaces (with certain limited exceptions) and enhances and expands current state regulations, passed the Maryland General Assembly on the last day of the 2007 session. Governor Martin O'Malley signed the bill, which

will go into effect on February 1, 2008. This legislation will make Maryland the 19th state to have such a wide-reaching ban on indoor smoking.

Another of the Center's major legislative victories is the Firefighter Protection and Cigarette Fire Safety Act. The law requires that cigarettes sold in Maryland meet certain fire safety standards designed to reduce accidental fires caused by cigarettes. Center staff and clinic students assisted in drafting the bill and the accompanying fiscal note, provided written and oral testimony in support of the bill to House and Senate committees, and coordinated the testimony of national fire safety experts. In April, the Act passed the General Assembly with a 136-1 vote in the House and a 46-0 vote in the Senate. Governor O'Malley recently signed the bill which will go into effect on July 1, 2008.

During the next legislative session, the Center plans to continue to work with state legislators on bills that would increase the penalties to retailers who sell tobacco to minors, protect foster children from exposure to secondhand smoke, and impose tobacco product placement restrictions on all Maryland retailers.

Tobacco Center: Work at the National Level

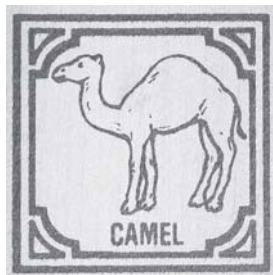
The Center's work is also expanding on the national level. Center Director Dachille helped found and is currently a Steering Committee member of the Tobacco Control Legal Consortium (TCLC), a national network created in 2002 to support tobacco control policy change by giving advocates better access to legal expertise. TCLC grew out of a collaboration among existing legal programs serving six states, including Maryland's Tobacco Center, the Technical Assistance Legal Center (California), the Tobacco Control Resource Center (Massachusetts), the Tobacco Law Center (Minnesota), Smokefree Environments Law Project (Michigan), and the Tobacco Control Policy Legal Resource Center (New Jersey). Recently, the TCLC added two

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CONFERENCE NEWS

“‘SAFER TOBACCO PRODUCTS’: REDUCING HARM OR GIVING FALSE HOPE?”

Camel cigarette’s iconic dromedary’s ears must have been burning on Friday, April 20, as the Law & Health Care Program and the Center for Tobacco Regulation, Litigation and Advocacy held the first national conference on the issue of “reduced harm” tobacco products.



Central to the discussion was whether Camel’s new, fashionably packaged chew tobacco product, Snus,

and other products like it have a role in the fight against tobacco-related illnesses. The conference, “‘Safer Tobacco Products’: Reducing Harm or Giving False Hope?,” brought together key scientists, policy makers and tobacco control advocates to discuss this timely and immensely important issue. Unlike nicotine replacement products, reduced harm tobacco products are alternative tobacco-related sources of nicotine, including smokeless tobacco products such as chew and snuff, and newly designed products such as the Marlboro Ultrasmooth. The primary issue addressed by conference speakers and attendees was whether these reduced harm products have a place at the tobacco control table, in other words, whether tobacco control advocates should embrace these products as a part of an overall tobacco control framework or embrace a policy of total abstinence from all tobacco products. An important related issue discussed at the conference was whether and how the federal and state governments can and should regulate the marketing and sale of such products.

Conference speakers traced the history of reduced harm products spending significant time on the public health

debacle of the “light” cigarette. Mitch Zeller, Vice President for Policy and Strategic Communications at Pinney Associates and former Executive V.P. of the American Legacy Foundation, reminded attendees that, when the causal relationship between cigarette smoking and lung cancer was first established in the 1950s, the tobacco industry began altering its products by adding filters to cigarettes, and then, in the 1960s, by marketing so-called “low tar and low nicotine” cigarettes. Twenty years later, after extensive testing, researchers determined that smokers who switched to light cigarettes did not reduce their lung cancer risk. In addition, research has shown that



*Mitch Zeller
Pinney Associates*

smokers switched to lower yield cigarettes out of concern for their health in the belief that these cigarettes were less risky or were a step toward quitting, when in fact the marketing and promotion of reduced yield cigarettes may actually have delayed genuine attempts to quit. Zeller suggested that the light cigarette experience should make us very cautious of tobacco industry attempts to introduce innovative products. To highlight this concept, Zeller discussed a recent survey in which individuals were asked about

their perceptions of the safety of the new Eclipse cigarette (a cigarette-like product sold by R.J. Reynolds that heats rather than burns tobacco to create an inhalable vapor). Twenty-four percent of respondents believed that Eclipse reduced the risk of using tobacco by 100% and 57% believed that it reduced the risk by 60-100%. The danger of these consumer assumptions is that they are based on express or implied advertising claims rather than on long-term scientific evidence – evidence that neither R.J. Reynolds nor the government has acquired on the Eclipse product.

This wariness on the part of the tobacco control community was echoed by various speakers and is primarily a result of two concerns: (1) how reduced harm products are marketed, and (2) suspicion regarding the major cigarette industries’ inroads into the smokeless tobacco market. Several speakers voiced concern that these products are being marketed to young people – with advertisements that feature concerts and “blondes” and flavors such as “spice” and “frost.” On another front, Zeller voiced concern that the products are marketed as “bridges” – products that can help smokers endure stretches of time (such as work or airplane rides) where smoking is not permitted. Zeller warned that providing and promoting such a bridge might actually make it harder for certain individuals to quit smoking cigarettes.

Geoffrey Ferris Wayne, of the Harvard School of Public Health, and Mitch Zeller both discussed the role that harm reduction products play in tobacco industry strategy. Wayne spoke of three relatively new tactics being embraced by the industry – U.S. companies making strategic acquisitions of international companies; brand proliferation (there are now over 2,000 different tobacco products on the market in the United

Cont. on page 6

States); and cross promotion of brands, e.g., Camel Snus. Zeller took suspicion of the industry one step farther by suggesting that tobacco companies are promoting smokeless tobacco products not to achieve a market success but to

risks related to smoking, Dr. Heaton argues that tobacco control advocates should not embrace these products but rather advocate for complete tobacco abstinence.

Dr. Mark Shields of Georgetown

University discussed the science behind risk reduction products and the difficulty in determining whether reduced exposure to tobacco actually leads to a reduction of the health risks posed by tobacco. Because public health advocates cannot wait for long term epidemiological studies to be completed on these products and because of the number of factors that contribute to an individual's tobacco-related risk level, Dr. Shields

concluded that any discussion of reduced harm products will involve some uncertainty. Shields asked conference attendees to think about how much uncertainty they would be willing to accept as they made policy in this area and, as a corollary, how much risk reduction is enough?

Two speakers, William Godshall of Smokefree Pennsylvania and David Sweanor of the University of Ottawa, made strong cases for accepting a decreased, but not complete, risk reduction by embracing the use of smokeless tobacco products. They both stressed the importance of accepting the grim realities of tobacco use and making the rational decision to promote reduced harm products for the statistically-established number of smokers who cannot or will not quit. Both speakers stressed that the tobacco control community, in its zealotry to fight the ravages of tobacco, may be abandoning

this group although substantial evidence exists that reduced harm products do offer smokers with a lower risk alternative to smoking. Sweanor argued that an "abstinence only" approach is "inconsistent with what science tells us about addiction and self-medication." Sweanor is further convinced that, if governments step in and regulate the smokeless tobacco market, the industry will produce innovative and safer products. The idea that regulation shapes the market can be seen, Sweanor points out, in the pharmaceutical, automotive, and food industries.

Several speakers provided legal and legislative updates in the area of reduced harm products. Micah Berman, Executive Director of the Tobacco Public Policy Center in Ohio, suggested a legal response to cigarette companies



(l-r) Dean Karen Rothenberg, Maryland Attorney General Douglas Gansler, Professor Kathleen Dachille

repair their tarnished image – a public image that plummeted because of tobacco litigation successes in the 1990s.

Douglas F. Gansler, Maryland's recently elected Attorney General, introduced the conference's keynote speaker, Dr. Cheryl Heaton. Dr. Heaton is the President and CEO of the American Legacy Foundation, a nonprofit public health organization created by the historic Master Settlement Agreement regarding tobacco. Dr. Heaton began her spirited comments by noting that tobacco control advocates are "jaded" after having been misled by the tobacco industry "for decades" and are, therefore, automatically suspicious of reduced harm products. From her perspective, reduced harm products are going to make it harder for nicotine addicts to quit smoking because tobacco industry marketing strategies will convince smokers that reduced harm products are a safer alternative. Because there is no evidence that such products eliminate the



*Micah Berman
Tobacco Public Policy Center*

"going smokeless," i.e., expanding and promoting their smokeless tobacco product lines. In Berman's view, although smokeless products may have a role in reducing the harm of tobacco, the motives and methods behind the industry's entrance into the market *does* matter because "their goal is not harm reduction." In fact, argues Berman, the industry undercuts its own claims of harm reduction by marketing to young people, people who have never smoked, and former smokers; by promoting the products as accompaniments, not

CHRIS BOSTIC JOINS TOBACCO CENTER

replacements, to combustible tobacco; and by not making these products as safe as possible. Berman suggested that addressing these issues should become policy goals for the tobacco control community.

Professor Richard Daynard from Northeastern University School of Law provided an update on tobacco litigation. He told the conference that “tobacco litigation matters” because it tarnishes the image of tobacco companies, forces the industry to raise the price of its products, and results in better settlements for plaintiffs. Both Daynard and Berman discussed a new dilemma that tobacco companies now face in promoting safer products. In a number of tobacco cases, plaintiffs lost because they could not show that there was a “feasible alternative design” to the cigarette. Companies presenting reduced harm products may be forfeiting this defense by selling a product that is, in fact, a feasible alternative. Both speakers suggested that the tobacco control community investigate this conundrum as a possible opening for litigation against the industry.

To round out a day of provocative discussion, Chris Bostic, a clinical instructor for the law school’s Tobacco Control Clinic and Legal Counsel to the Framework Convention Alliance, and Dr. Vera Luiza da Costa e Silva, former director of the Tobacco Free Initiative at the World Health Organization, gave attendees an update on the implementation of the WHO’s landmark Framework Convention for Tobacco Control and international perspectives on reduced exposure products.

Many speakers and attendees agreed that the conference was invaluable in bringing forward the two sides of this issue and a good base upon which to form a coherent set of future policy recommendations. The burning in the camel’s ear is likely to become a deafening roar in the years to come.

This year, the Tobacco Control Center added international tobacco control efforts to its scope of work. To foster this new endeavor, the Center hired Chris Bostic, legal counsel to the international Framework Convention Alliance for Tobacco Control (FCA). Bostic joined the Tobacco Center in the fall of 2006 as a consultant and in 2007 became a clinical instructor, working with students in the tobacco control clinic. Bostic’s primary role within the Center is to serve as a liaison with the global tobacco control community and to identify and attract global clients to the Center’s Tobacco Control Clinic.

Bostic brings years of domestic and international experience in the world of tobacco control to his work at the Center. Bostic gained his first exposure to tobacco control as a student attorney at the Campaign for Tobacco-Free Kids while attending American University Washington College of Law in Washington, D.C. He then went on to work at the American Lung Association as a Program Manager.

As a clinical instructor in the tobacco control clinic, Bostic has been working with students to identify potential legal conflicts for countries that arise when they attempt to implement measures to encourage alternatives to tobacco crops and also carry out trade agreement obligations, particularly obligations related to membership in the World Trade Organization. This project stems from the ongoing discussion on the international level regarding tensions between trade and tobacco control. According to Bostic, this discussion has focused almost entirely on demand-reduction strategies, i.e., warning labels on cigarette packages, advertising and marketing, etc. The students’ research is designed to assist policy makers on how to avoid being dragged into a trade court for tobacco growing policies.



Chris Bostic

When Bostic is not working with the Center, he is either consulting for the FCA or the Tobacco Control Legal Consortium. The FCA is a coalition of over 200 organizations and networks from more than 90 countries working to support the Framework Convention on Tobacco Control, the landmark international tobacco control treaty that was negotiated by the 192 member states of the World Health Organization (WHO). Working on similar issues at a national level, the Tobacco Control Legal Consortium is a national network supporting tobacco control policy change by giving advocates better access to legal expertise.

In February, Bostic took two University of Maryland law school students to Brasilia, Brazil for the first meeting of the Framework Convention on Tobacco Control’s Ad Hoc Study Group on Alternative Crop (*see* article, p. 8.)

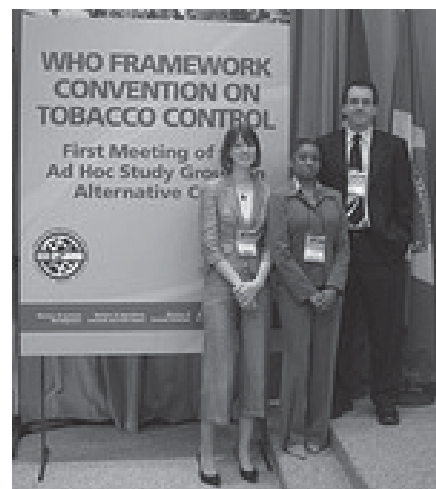
Also, in keeping with his life of globe-trotting advocacy, Bostic will attend the second session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control in Bangkok, Thailand in June.

TOBACCO CLINIC STUDENTS ATTEND CONFERENCE IN BRASILIA

In February 2007, Chris Bostic, the Tobacco Control Center's new clinical instructor, took two law school students, Lauren Willis and Alva Wright, to Brasilia for the first meeting of the Ad Hoc Study Group on Alternative Crops. This study group was convened as part of the World Health Organization Framework Convention on Tobacco Control (FCTC). Article 17 of the FCTC mandates that parties to the convention "promote, as appropriate, economically viable alternatives for tobacco workers, growers and, as the case may be, individual sellers." Policy makers in this area believe that tobacco growers should substitute

alternative crops for tobacco or engage in alternative livelihoods not only because of market forces (basic economic principles dictate that a decrease in demand for tobacco products will result in a drop in price) but also because of the negative health and social issues associated with the cultivation of tobacco. (As a side note, the most successful transition to alternative crops worldwide has taken place in Maryland, where there has been an 80% reduction in the amount of tobacco grown.)

At an open meeting on the first day of the study group's gathering in Brasilia, the Maryland contingent represented the



(l-r) Lauren Willis,
Alva Wright, Chris Bostic

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ALUM WORKING AT W.H.O. ON INTERNATIONAL TOBACCO CONTROL

Gemma Vestal ('02) doesn't spend much time in the Geneva headquarters of the World Health Organization (WHO) where she serves as Legal Officer and Scientist for the WHO's Tobacco Free Initiative (TFI). In 2006, Vestal's position took her to such places as France, Turkey, Canada, Japan, Germany, Norway, and back here to the United States to focus international attention, resources and action on the global tobacco epidemic. Established in July 1998, the TFI's objective is to reduce the global burden of disease and death caused by tobacco, thereby protecting present and future generations from the devastating health, social, environmental, and economic consequences of tobacco consumption and exposure to tobacco smoke. To accomplish its mission, the TFI provides global policy leadership, encourages mobilization at all levels of society, and promotes the WHO Framework Convention on Tobacco Control by encouraging countries to adhere



Gemma Vestal

to its principles and supporting them in their efforts to implement tobacco control measures based on its provisions. In the last year, Vestal met several times with key stakeholders to develop guidelines for the implementation of Articles 9 and 10 of the FCTC relating to the contents of tobacco products and disclosure of those contents. She has also worked with experts to discuss the best ways to translate data gathered under the FCTC into meaningful

regulatory tools. Vestal calls her job "incredibly challenging and rewarding."

Vestal earned her J.D. from the law school in 2002. While she was here, she served as Associate Editor of the *Journal of Health Care Law & Policy* and was a Board Member of the Student Health Law Organization. Vestal also has an MPH from the Johns Hopkins Bloomberg School of Public Health, an MBA from the University of Baltimore, and a BS in Nursing. Vestal hasn't always worked at the highest level of international policy making – she also worked on the ground as a flight nurse in California for two years. Vestal is an inspiration for all health law students who work as interns and law clerks in health law organizations. What Vestal calls a "serendipitous" week-long legal internship with the World Health Organization in July 2002 led to her current position. The conference was held at the United Nations in New York and Vestal's participation in the conference was arranged by L&HCP faculty member, Allyn Taylor.

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FACULTY AT THE FOREFRONT OF HEALTH POLICY

U.S. DEPARTMENT OF JUSTICE OPENS INVESTIGATION INTO BALTIMORE'S ZONING STANDARDS AT URGING OF LAW SCHOOL'S DRUG POLICY CLINIC

There are 58,000 citizens in Baltimore who need drug treatment every year. But, according to Professor Ellen Weber and her Drug Policy Clinic students, Baltimore's discriminatory zoning standards prevent those residents from getting the appropriate community-based care that they need. And they've gotten an important watchdog to listen to their allegations. Based on a complaint filed by the students with the Disability Rights Section of the Civil Rights Division of the United States Department of Justice (DOJ), the Assistant Attorney General for Civil Rights has recently agreed to open an investigation of the clinic's complaint that Baltimore City's zoning standards for residential drug treatment discriminate against individuals with histories of drug dependence.

Drug treatment programs, unlike any other outpatient or residential health care services, are required to get community approval and secure passage of zoning legislation to open a facility or expand existing services in any location in the city. The zoning process, known as the conditional use ordinance, dates back to the early 1960s. It was created and incorporated into the City's Zoning and Health Codes for the explicit purpose of permitting communities to exclude drug treatment programs because of the clients who would be served. Currently, the City Council and other city officials perpetuate this discriminatory standard by refusing to introduce or support a treatment program's zoning legislation if community associations in the area of the proposed facility oppose the siting of the program in their neighborhood.

Community associations frequently refuse to provide their approval based on negative stereotypes stemming from an unfounded fear of individuals who require alcohol or drug treatment. In addition to the community approval requirement, the conditional use ordinance process also requires those attempting to site treatment programs to participate in two separate public hearings and expend significant resources to navigate the political process. These time-consuming and cost-prohibitive

efforts are not required of other similarly-situated health care providers.

These combined requirements have resulted in the denial of zoning permits to drug and alcohol treatment programs – including programs that have served the City's residents for many years with exemplary records. The students' complaint documents the zoning process, its history and current use, and individual

cases of intentional discrimination.

Professor Ellen Weber, faculty member since 2002 and former Senior Vice President for the Legal Action Center, created the Law School's Drug Policy and Public Health Strategies Clinic to address practices that inhibit the expansion of drug treatment in communities and the criminal justice system and discriminate against individuals with histories of drug dependence. To address the addiction issues that drive much of the crime in certain Baltimore neighborhoods, Weber and her students use legal and policy advocacy strategies to both force and encourage the City to provide better health care services.

This recent success with the DOJ investigation comes on the heels of the enactment of zoning legislation by the Baltimore City Council that invalidated discriminatory zoning standards that have banned outpatient drug treatment programs from many communities. The Drug Policy Clinic had worked for four

years with its client, a coalition of the City's drug treatment providers, and other advocates in the community to persuade the City to enact this legislation. The DOJ investigation is expected to resolve the remaining zoning barriers to the expansion of treatment services.

In addition to her work at the law school, Professor Weber is part of an interdisciplinary team of University of Maryland faculty examining substance abuse issues within the professions. She is also participating on a Health Care Advisory Workgroup convened by the Maryland Departments of Health and Mental Hygiene and Human Resources that is identifying options to improve the health care delivery system for Baltimore children in foster care.



Ellen Weber

L&HCP FACULTY PRESENT PAPER ON ALTERNATIVES TO QIOs FOR MEDICARE BENEFICIARY COMPLAINTS

John Q., the son of a 72 year old nursing home resident, believes that his father, Robert, has not been getting adequate care at the nursing home. Robert has had several decubitus ulcers. Who should John contact to complain about Robert's care?

Although the nursing home ombudsman or the state survey and licensing agency would be obvious choices, Medicare beneficiaries concerned about the quality of health care they receive are instructed to contact their local QIO – Quality Improvement Organization – to lodge a complaint. QIOs are the federal government's primary tool for assuring that services provided to Medicare beneficiaries are medically necessary, of a quality that meets professionally recognized standards of health care, and provided in an appropriate setting. The government spends approximately \$400 million a year on the QIO program, which includes 41 contractors who cover all 50 States and Washington D.C., Puerto Rico, and the Virgin Islands.

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QIOs that receive a complaint from a beneficiary are required, at a minimum, to notify a complainant of the results of a review and to disclose their determinations as to whether the quality of the services that the recipient received met professionally recognized standards of health care.

Despite being funded to provide this service, there have been numerous criticisms levied at QIOs in carrying out the complaint review process. These criticisms have been voiced through reports prepared by the Office of the Inspector General (OIG) and the Institute of Medicine (IoM) which state that QIOs: 1) receive very few complaints because beneficiaries are generally unaware of the complaint process; 2) do not provide complainants with meaningful, substantive responses to their complaints and take too long to respond; 3) resolve very few complaints and take limited action in response to substantiated complaints. In 2006, the IoM, as a result of its findings, recommended removing the function of performing quality of care investigations from the QIOs and allowing other entities to perform this work while QIOs continue to focus more specifically on assisting health care providers in quality improvement.

In response to the IoM recommendation, and with support from The Commonwealth Fund, the Center for Medicare Advocacy commissioned two papers, one by Professor Diane Hoffmann and L&HCP Coordinator Virginia Rowthorn, to explore possible alternative entities that might carry out the complaint process, and a second by Dr. Peter Hollmann, to examine the attributes of an ideal complaint process. In January of this year, the Center staff, led by Judith Stein and Alfred Chiplin, convened a working conference, at which Hoffmann, Rowthorn and Hollmann presented their papers. The purpose of the conference was to design a "model" complaint process for Medicare beneficiaries.

The conference provided a forum for key stakeholders to discuss concerns and develop a blueprint for change. Forty-two invited experts from a variety of backgrounds attended the conference. They included Barry Straube, Chief Medical Officer and Director of the Office of Clinical Standards and Quality at the Centers for Medicare & Medicaid

Services; David Schulke, Executive Vice President of the American Health Quality Association; Lisa Robin, Vice President of Government Relations, Policy, and Education for the Federation of State Medical Boards; Julie Taitsman, Special Counsel for Health and Science for the U.S. Senate Committee on Finance; and, Eleanor Kinney, Co-Director of the Hall Center for Law and Health at the Indiana University School of Law.

Hoffmann and Rowthorn's paper, which provided the backdrop for the discussion of



a model complaint process, reviews the literature on the performance of QIOs in responding to Medicare beneficiary complaints, sets forth criteria for evaluating a Medicare beneficiary complaint process, and uses the criteria to assess how existing entities that already conduct similar work, e.g., state medical boards and state survey agencies, would fare as possible alternatives to QIOs in responding to Medicare beneficiary complaints. Hoffmann and Rowthorn concluded that, while these alternative entities have considerable experience responding to complaints from consumers and patients about health care quality and fare better on a number of evaluative criteria than QIOs, they also have weaknesses that would make it difficult to rely on them in their current form to undertake this task. Chief among these weaknesses is the variation in these entities from state to state, the limited scope of authority of the state survey agencies (i.e., to institutional providers) and state medical boards (to physicians), and the limited oversight the federal government has over state medical boards. A copy of Hoffmann and Rowthorn's paper, along with

the recommendations of the conference working group, is available at <http://www.medicareadvocacy.org/projects/QIOConference.htm>.

L&HCP DIRECTOR ADDRESSES EPIDEMIOLOGISTS ON LIABILITY RELATED TO HEALTHCARE ACQUIRED INFECTIONS

According to the U.S. Centers for Disease Control and Prevention, health care acquired (or nosocomial) infections cause 90,000 deaths per year in the United States and result in an estimated eight million excess hospital days and more than \$5 billion in excess healthcare costs each year. The microbe that causes the majority of serious nosocomial infections is methicillin-resistant staphylococcus aureus or MRSA. MRSA lurks on the body of one in every 20 patients entering the hospital¹ and research has shown that of those patients who have it on their bodies at admission, up to one in five develops an infection.²

To address this problem, some hospitals are taking steps to identify patients carrying MRSA when they are admitted to the hospital or ICU. Patients who are identified as having the infection are isolated and treated appropriately. This strategy, called surveillance screening or universal surveillance, has proven extremely successful in Denmark and the Netherlands, both of which have brought the level of MRSA infection in hospitals down to almost nonexistent.³ At Boston's Brigham and Women's Hospital, high-compliance screening for MRSA in adult ICUs led to dramatic decreases in MRSA bloodstream infections throughout the hospital.

While some hospitals are implementing surveillance screening, others are nervous about the potential legal liability associated with such screening programs. The information generated by such surveillance is one issue that makes some hospitals nervous. In addition, a number of states are passing bills requiring mandatory reporting of nosocomial infections. This data may ultimately be used to compare rates of nosocomial infections across all

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FACULTY & STUDENTS IN AFRICA

UMD LAW STUDENT VISITS KENYA WITH THE BUSINESS WOMEN'S INITIATIVE AGAINST HIV/AIDS

In 2006, because of her expertise on women and AIDS issues both nationally and around the world, Karen Rothenberg, Dean of the University of Maryland Law School, was asked to serve as academic advisor to the Business Women's Initiative Against HIV/AIDS (BWI). BWI, the brainchild of Mary Robinson, former United Nations High Commissioner for Human Rights and President of Ireland, and Mary Ann Leeper, President and Chief Operations Officer of the Female Health Company, is an alliance of business leaders and nongovernmental organizations (NGOs) created to bring innovative and holistic approaches to help empower women with the education and interventions to protect themselves from HIV/AIDS.

In November, Dean Rothenberg invited Andrea Vaughn, a joint JD/MPH student, to represent her during BWI's first fact-finding mission to Africa. Andrea joined a group of prominent BWI members on this landmark visit which took them to Nairobi and Kisumu, Kenya.

BWI's goal is to create links between business women in the United States and Europe with women leaders in Africa who have demonstrated their expertise in working within their communities. One of BWI's primary goals is to promote the availability and use of the female condom – the only available method to prevent HIV/AIDS that is under a woman's control. BWI has voiced its concern that, despite the proven effectiveness of the female condom, bureaucracy, shortage of funds, and lack of commitment to women are thwarting the broad distribution of these products to those most in need. BWI also advocates further research and development of microbicides as a critical preventive technology that will greatly empower women in the coming years.



Andrea Vaughn '07 (center)

The group met with members of the Kenyan parliament, government officials, representatives of local and international NGOs, business leaders and local attorneys. Andrea and the rest of the group also had the opportunity to visit several nonprofit organizations including the Girls Empowerment Programme, Girl Guides Project, Leo Toto (a nutritional care program for children infected by HIV), Women Fighting AIDS in Kenya (WOFAK), and the Federation of Kenyan Women Lawyers (called FIDA). FIDA is one of the only groups in Kenya that provides legal services to women – mainly handling cases relating to alimony, succession, violence, genital mutilation, and property claims.

Andrea, who has traveled overseas extensively and served as a Peace Corps volunteer in Ecuador, was deeply moved by her experience in Africa. One of the greatest lasting impressions she came away with was the enormous dedication of the women working on the ground to improve the lives of women and children in Kenya – “I believe more than ever that we don't have the answers – these women have the answers, or as close as there are to answers, and we need to find a way to support their efforts.”

ROTHENBERG ADDRESSES UNIVERSITY OF CAPETOWN LAW SCHOOL ON THE DEADLY INTERSECTION OF DOMESTIC VIOLENCE AND HIV/AIDS

In March, Dean Karen Rothenberg visited Capetown, South Africa, to formalize a faculty/student exchange program between our law school and the University of Capetown Law School. While there, she addressed a group of law school faculty and students as well as representatives of local legal aid organizations. In her talk entitled “The Intersection of Domestic Violence and HIV/AIDS: Learning from the Past, Lessons for the Future,” Rothenberg



Karen Rothenberg with University of Maryland law students Jessica George, Brigid Ryan, and Melissa Hill in Capetown★

told the story of the law school's early encounters with the now well-documented intersection of these two public health crises. In 1987, two of the law school clinic's female clients were assaulted when their partners learned of their HIV status. This prompted Rothenberg to study the issue of partner notification in greater depth and plan the

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FOCUS ON EXTERNSHIPS . . . BRIAN KEHOE

OFFICE OF LEGISLATION/FDA

The health law externship program at the University of Maryland School of Law allows students the opportunity to gain valuable experience in a variety of government and non-profit settings. During the Spring semester, I spent two days a week in the Office of Legislation (OL) at the U.S. Food and Drug Administration (FDA).

The OL serves as the liaison between Congress and the Agency and has provided me with a window into the real-world workings of the U.S. regulatory system. The OL staff spend the majority of their time on two broad tasks. First, OL responds to all of the congressional inquiries received by the Agency. These inquiries vary substantially and might deal with general policies or be specific to an individual constituent. The OL also takes the lead when the FDA testifies before Congress. This involves drafting testimony and reviewing pending legislation, and requires an understanding of the issues and current political climate.

The office is made up of three teams which specialize respectively on food, drugs, and biological products. Team members develop specific expertise but there is extensive collaboration. For example, each Congressional hearing is assigned to one team member. While a hearing will focus on one issue, the FDA witness must be prepared to answer a range of questions from members of Congress. Team members work together to brief the witness on the hot issues likely to arise during the hearing.

I have been working on the drugs team, which has allowed me to get involved in a wide range of activities. Initially, I was given responsibility for responding to Congressional inquiries into drug importation. Drug importation has been a hot issue in the last few years due to the high prices of U.S. brand name drugs compared to their foreign counterparts. Many Americans have sought to purchase cheaper drugs through online pharmacies that offer foreign drugs at lower prices. Such personal drug importation violates federal

law. Foreign drugs are produced outside of the U.S. regulatory system and without assurances that these drugs are safe and effective. Although there is a real potential that these foreign drugs might be counterfeit with harmful ingredients, there are also more potential subtle dangers. Drugs are manufactured under complicated specifications designed to ensure standardization. Foreign drugs might be more or less potent and might not enter the bloodstream at the same rate as those manufactured in the U.S.

While the FDA does not have the resources to inspect a large percentage of incoming packages, the FDA does intercept a portion of imported drugs. Many individuals contact their Congressional representatives who, in turn, request information from the FDA about the status of their packages. When I received these requests, I would contact the field inspectors to learn the details of the detention. I then would contact the Congressional staff to explain the FDA's role in enforcing federal law and the details of the specific detention. There were also instances where, based on the information I received, FDA decided to release the imported drug. This happened, for example, when there was not a U.S. version of the foreign drug and the drug was required to treat a serious condition.

I also had the opportunity to help in the preparation for and attend several congressional hearings. In March, the Senate Committee on Health, Education, Labor, and Pensions held a hearing to consider reauthorizing the Prescription Drug User Fee Act (PDUFA). PDUFA was originally passed in 1992 and provides increased funding for the FDA through industry fees. I drafted the Commissioner's written testimony using previous PDUFA testimony, Federal Register documents, and

internal materials. The written testimony I helped to prepare for the Commissioner will appear in the Federal Register. I joined several briefing sessions where senior FDA staff members and the Commissioner discussed areas of potential Congressional concern. After attending the hearing, I prepared a hearing report detailing the views of the different witnesses and the concerns that were raised.

My externship experience at the FDA has been a valuable aspect of my legal education. I encourage other students to take advantage of the varied opportunities that are available through the Law & Health Care Program.



Brian Kehoe

Brian, who graduated this spring with the Health Law Certificate, also interned at Greater Boston Legal Services, MedImmune, and the American Pain Foundation during his three years at the law school. Brian was recently chosen as a Presidential Management Fellow, a two year paid government fellowship sponsored by the Office of Personnel Management. Although Brian could have chosen positions in other branches of the government, he has decided to remain at the FDA's Office of Legislation for his fellowship.

L&HCP FACULTY NOTES ...

FROM MAY 2006 TO MAY 2007

Richard Boldt

ARTICLES:

"Juristocracy in the Trenches: Problem-Solving Judges and Therapeutic Jurisprudence in Drug Treatment Courts and Unified Family Courts," 65 *Maryland Law Review* 82 (2006) (with Jana Singer)

Kathleen Dachille

PRESENTATIONS:

Debate, "Does Parental Smoking Constitute Child Abuse? Striking the Rights Balance," The National Center for Adoption Law & Policy, Capital University School of Law, Columbus, Ohio (October 6, 2006)

"Employment Policies Based on Smoking Habits," Making the Business Case for Smoking Cessation and Tobacco Control, Wolfe Symposium, Columbus, Ohio (October 6, 2006)

"Policy and Legislation to Reduce Tobacco Use and Tobacco-Related Disease in Maryland," Maryland Cancer Council Annual Meeting, Baltimore, Maryland (November 15, 2006)

Michael Greenberger

ARTICLES:

"The Alfonse and Gaston of Governmental Response to National Public Health Emergencies: Lessons Learned from Hurricane Katrina for the Federal Government and the States," 58 *Administrative Law Review* 611 (2006)

"False Conflict: Who's In Charge of National Public Health Catastrophes," 31 *Admin. & Reg. L. News* 2 (2006)

"Choking Bioshield: The Department of Homeland Security's Stranglehold on Biodefense Vaccine Development," 1 *Microbe* 260 (2006)

"Preparing Vulnerable Populations for a Disaster: Inner-City Emergency Preparedness – Who Should Take the Lead?," 10 *DePaul J. Health Care L.* 291 (2007)

PRESENTATIONS:

"Community Impacts – Potential System Breakdowns and Community Response in the Event of a Pandemic Flu," Howard County Pandemic Flu Summit, Columbia, Maryland (May 16, 2006)

"Public Health: The Next Pandemic," Panelist, 30th Annual Health Law Teachers Conference, University of Maryland School of Law, Baltimore, Maryland (June 2, 2006)

"Pandemic Flu and Crisis Management Planning: How Can Immigrants Be Involved and Prepared," Panelist, Maryland Coalition for Refugees and Immigrants Conference, Anne Arundel Community College, Arnold, Maryland (June 14, 2006)

"Bioshield and Vaccine Commercialization," Middle Atlantic Regional Center of Excellence in Biodefense and Emerging Infectious Disease Research (MARCE) Fall Meeting, University of Virginia School of Medicine, Charlottesville, Virginia (October 18, 2006)

"The Public's Health and the Law in the 21st Century: A Public Health Legal Preparedness Summit," Invited Participant, Center for Disease Control Planning Meeting, Atlanta, Georgia (October 20, 2006)

"Using Legal Preparedness to Build Partnerships with the Private Sector," Panelist, American Public Health Association Partnership Breakfast, Boston, Massachusetts (November 6, 2006)

"Is Anyone or Everyone in Charge? Responding to Regional Catastrophic Public Health Events," Organizer and Facilitator, Middle-Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research (MARCE) Emergency Preparedness Conference, Uniformed Services University of the Health Sciences, Bethesda, Maryland (February 27, 2007)

Deborah Hellman

ARTICLE:

"Physicians as Researchers: Difficulties with the 'Similarity Position'," *American Journal of Bioethics*, July/Aug. 2006, at 57 (with D. Wasserman & R.S. Wachbroit)

Diane Hoffmann

ARTICLES:

"The Legal Column: Choosing Paternalism?," *Lahey Clinic Medical Ethics*, Vol. 13, Issue 2, p. 4 (Spring 2006)

"Who decides whether a patient lives or dies?," *Trial*, Vol. 42, No. 10, pp. 30-37, (October 2006) (with Jack Schwartz)

"A Statewide Survey Identifying Perceived Barriers to Hospice Use in Nursing Homes," *Journal of Hospice and Palliative Nursing*, Vol. 8, No. 6, pages 1-10 (November/December 2006) (with Anita Tarzian)

"The Role and Legal Status of Health Care Ethics Committees in the U.S.," in

LEGAL PERSPECTIVES IN BIOETHICS: ANNALS OF BIOETHICS SERIES (Sandra Johnson & Ana Iltis, eds.) (book chapter) (with Anita Tarzian)

“Legal Issues in the Treatment of Pain,” in *COMPLICATIONS IN REGIONAL ANESTHESIA & PAIN MEDICINE*, Joseph M. Neal and James P. Rothwell (eds.) (Saunders Elsevier, 2007) (book chapter)

“Can State Medical Boards Adequately Respond to Reports that Physicians are Inappropriately Prescribing Opioids?,” 81 *Clinical Pharmacology & Therapeutics* 799 (2007)

PRESENTATIONS:

“Resuscitation at the End of Life,” Hospice Network of Maryland Annual Meeting, Baltimore, Maryland (November 1, 2006)

“The Medicare Beneficiary Complaint Process: QIO’s and Possible Alternatives,” keynote speaker, Center for Medicare Advocacy Conference, Washington, D.C. (January 19, 2007)

“Futility & Medically Inappropriate Care: Policy Approaches to Limiting Health Care at the Margins,” Conference sponsored by the Maryland Healthcare Ethics Network on “Money and Medicine: Bedside Ethics of the Medical Marketplace,” Greater Baltimore Medical Center, Baltimore, Maryland (January 30, 2007)

“Legal Issues Associated with Nosocomial Infections,” Patient Safety Symposium, University of Maryland Medical System, Baltimore, Maryland (January 30, 2007)

“Legal Obstacles to the Treatment of Chronic Pain,” ABA Mid-Winter Meeting, Section of Labor and Employment Law, Workers’ Compensation Committee, Naples, Florida (March 2, 2007)

“Judging Genes: Judicial Response to the Second Generation of Genetic Tests,” Program in Genetics and Genome Medicine Seminar Series Presentation, University of Maryland School of Medicine, Baltimore, Maryland (March 14, 2007)

“Law and Order: The Changing Legal Landscape Around Healthcare Associated Infections,” The Society for Healthcare Epidemiology of America, Baltimore, Maryland (April 15, 2007)

“Maternal Immunization: Liability and Other Legal Issues,” The Tenth Annual Conference on Vaccine Research, Baltimore, Maryland (May 1, 2007)

APPOINTMENTS:

CDC Advisory Committee on Immunization Practices (ACIP) workgroup on vaccines during pregnancy and breastfeeding.

Karen Rothenberg

ARTICLES:

“National Institutes of Health State-of-the-Science Conference Statement on Cesarean Delivery on Maternal Request,” 107 *Obstetrics and Gynecology* 1386 (2006)

“The Scarlet Gene: Behavioral Genetics, Criminal Law, and Racial and Ethnic Stigma,” 69 *Law and Contemporary Problems* 343 (2006) (with Alice Wang)

PRESENTATIONS:

“Judging Genes: Judicial Response to the Second Generation of Genetic Tests,” Southeastern Association of Law Schools Annual Meeting, Palm Beach, Florida (July 17, 2006)

“The Intersection of Domestic Violence & HIV/AIDS,” Faculty Presentation, University of Cape Town, South Africa (March 20, 2007)

OTHER ACTIVITIES/ APPOINTMENTS/AWARDS

Maryland Stem Cell Commission (2006–2008)

Board Member, Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. (2006–present)

Congressional Testimony, “Protecting Workers from Genetic Discrimination,” Committee on Education and Labor at the Subcommittee on Health, Employment, Labor and Pensions (HELP), Washington, D.C. (January 30, 2007)

Lawrence Sung

ARTICLES:

“License to Sue? The Availability of Declaratory Judgment Actions to Patent Licensees After *MedImmune, Inc. v. Genentech, Inc.*,” *Intellectual Property Today* (January 2007)

PRESENTATIONS:

“Can I Get There From Here?,” 56th Annual Meeting of the American Society of Human Genetics, New Orleans, Louisiana (October 10, 2006)

OTHER ACTIVITIES/
APPOINTMENTS/AWARDS

Interview, “High Court Backs MedImmune,” *Baltimore Sun* (January 10, 2007)

Allyn Taylor*

ARTICLES:

“Global Health Law,” *ENCYCLOPEDIA OF PUBLIC HEALTH* (Elsevier Science, 2006)

“A Guide to the Domestic Implementation of the WHO Framework Convention on Tobacco Control,” *Framework Convention Alliance* (2006)

PRESENTATIONS:

“The WHO Framework Convention on Tobacco Control and Global Health Lawmaking,” Georgetown University Law Center, Washington, D.C. (October 24, 2006)

“Health Security, Human Security and Human Rights” International Health Law and Policy 2006: Health, Ethics, Human Rights and International Regimes Conference, organized by the National University of Taiwan College of Law Asian Center for the WTO and International Health Law and Policy and the Taiwan Department of Health, Taipei, Taiwan (December 4, 2006)

“SARS: What Really Happened and Why International Health Law and Policy Will Never Be the Same,” with Dr. Jamie Maguire, University of Maryland School of Medicine Department of Epidemiology Seminar Series, Baltimore, Maryland (December 14, 2006)

OTHER ACTIVITIES/
APPOINTMENTS/AWARDS

Committee Member, Gates Global Health and Foreign Policy Initiative Appointments Committee, The Johns Hopkins University Paul H. Nitze School of Advanced International Studies, Washington, D.C. (September 2006 – Present)

Invitation, “Establish a UNESCO Bioethics Collaborating Centre, UNESCO Chair in Bioethics (2007)

Robin Wilson**

ARTICLE:

“The Challenge of Regulating Known Unknowns,” 34 *Journal of Law, Medicine & Ethics* 704 (Winter 2006)

PRESENTATIONS:

“Publishing Strategies for Health Law Teachers,” Moderator and Presenter, Health Law Teachers Conference, University of Maryland School of Law, Baltimore, Maryland (June 1, 2006)

“Nanotechnology: The Challenges of Regulating Known Unknowns” American Academy of Nanomedicine, Second Annual Conference, National Academy of Science, Washington, D.C. (September 11, 2006)

“Medicare: Where’s The Common Sense? A Response to Medicare Meets Mephistopheles by David A. Hyman,” Cato Institute, Washington, D.C. (September 21, 2006)

“Keynote: Consent: The Law and Hysterectomy,” HERS Foundation, Twenty-Fifth Annual Hysterectomy Conference, Nashville, Tennessee (October 28, 2006)

“Matters of Conscience: Evaluating the Duty to Dispense Emergency Contraceptives,” University of Virginia School of Medicine, Medical Center Hour, Charlottesville, Virginia (October 18, 2006)

OTHER ACTIVITIES/
APPOINTMENTS/AWARDS

Guest, Book Notes on C-Span, “Medicare Meets Mephistopheles by David A. Hyman discussion” (October 22, 2006)

*During the 2006–2007 academic year, Allyn Taylor had a joint appointment at the University of Maryland Schools of Medicine and Law. Next year, she will be joining the faculty at Georgetown University School of Law as a Visiting Professor.

**During the 2006–2007 academic year, Robin Wilson was visiting at Washington & Lee University School of Law. Next year she will be joining the faculty there.

Focus on Tobacco Regulation

Cont. from p. 3

States signed the treaty but President Bush has not yet sent the treaty to the U.S. Senate for ratification. The White House has said that it is continuing to study the treaty. Senate ratification would permit the U.S. to participate as a full party when the treaty's governing body, called the Conference of the Parties, meets to discuss implementation, funding and enforcement of the FCTC.

The early success of the treaty reflects strong support from the developing world. Some have attributed this to the increasingly "inequitable distribution of tobacco-related deaths, 70 percent of which will occur in developing countries by 2030."¹³ Support for the treaty may have also been a result of an influential report from the World Bank, "Curbing the Epidemic," which "helped reverse the longstanding perception that the tobacco industry was economically too beneficial to developing countries to allow for effective health regulation."¹⁴ The treaty gained widespread support despite efforts by the tobacco industry and international tobacco growers to undermine its passage. Next steps for implementation include putting in place the necessary infrastructure in each country and incorporating the treaty provisions into national laws. WHO is providing guidelines and materials to assist countries in this effort.

Renewed Efforts at the Federal Level

In 1996, the Food and Drug Administration (FDA) asserted jurisdiction over tobacco products under the Food, Drug, and Cosmetic Act through proposed regulations designed to regulate tobacco advertising, promotional campaigns, labeling and purchasing restrictions. The tobacco industry sued

the federal government, arguing that the FDA lacked legal authority to regulate tobacco products. The Supreme Court ruled in June 2000 that Congress had not expressly given the FDA legal authority to regulate the tobacco industry and that Congress must specifically enact



legislation to allow the FDA to regulate tobacco. As a result, all FDA tobacco regulations were dropped, including the federal minimum age requirement (18 years old) for tobacco products and federal rules requiring retailers to check photo identification.

On February 15, 2007, U.S. Senators Edward M. Kennedy (D-MA) and John Cornyn (R-TX) and U.S. Representatives Henry A. Waxman (D-CA) and Tom Davis (R-VA) introduced identical, bipartisan bills (S. 625/H.R. 1108) to grant the FDA authority to regulate tobacco products.¹⁵ This legislation has been strongly endorsed by the American

Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids, and numerous public health, faith and other organizations around the country.

This legislation would grant the FDA enormous authority to regulate both current and new tobacco products and restrict tobacco product marketing. The bills require that the FDA's 1996 Rule (referenced above) be republished within one month and take effect within one year of enactment of the legislation. Specifically, these rules:

- Ban all outdoor tobacco advertising within 1,000 feet of schools and playgrounds.
- Ban all remaining tobacco brand sponsorships of sports and entertainment events.
- Ban free giveaways of any non-tobacco items with the purchase of a tobacco product or in exchange for coupons or proof of purchase.
- Ban free samples and the sale of cigarettes in packages that contain fewer than 20 cigarettes.
- Limit any outdoor and all point-of-sale tobacco advertising to black-and-white text only.
- Limit advertising in publications with significant teen readership to black-and-white text only.
- Restrict vending machines and self-service displays to adult-only facilities.
- Require retailers to verify age for all over-the-counter sales and provide for federal enforcement and penalties against retailers who sell to minors.

The FDA's authority in these areas would not be limited to provisions of the 1996 Rule. The FDA could take additional regulatory steps to restrict tobacco marketing and to prevent tobacco sales to persons under 18. The legislation would also:

- Grant the FDA specific authority to restrict tobacco marketing.
- Require detailed disclosure of ingredients, nicotine and harmful smoke constituents.
- Empower the FDA to establish a periodically re-evaluated content standard, and require changes in tobacco products to meet the standard.
- Ban all cigarette flavorings other than menthol, that are a characterizing flavor of the product.
- Ban the use on labels or in advertising of terms such as “light,” “mild,” or “low.”
- Strictly regulate “reduced harm” products.
- Require bigger, better, health warnings.
- Establish a Tobacco Products Scientific Advisory Committee.
- Fund FDA activity through a fee on tobacco product manufacturers, allocated by market share.
- Eliminate existing federal preemption of state laws restricting cigarette advertising.
- Protect states’ ability to pass other tobacco control laws.¹⁶

A poll commissioned by the Campaign for Tobacco-Free Kids found that 77% of registered voters support giving the FDA the power to regulate tobacco products.¹⁷ The survey of 800 voters, conducted by Public Opinion Strategies and the Mellman Group, found that support for FDA regulation cut across political and regional lines, and was backed by strong majorities of smokers and nonsmokers. The poll also found strong support for specific regulatory steps like limiting advertising in publications with large underage readerships, regulating relative health claims about tobacco products, and

requiring tobacco companies to reduce or remove harmful substances from cigarettes, including nicotine.¹⁸ Both bills have been referred to Committee – the Committee on Health, Education, Labor, and Pensions on the Senate side and the Committee on Energy and Commerce on the House side. Tobacco control advocates are anxiously awaiting further Congressional action on a bill that would dramatically change the legal landscape of both tobacco use and control.

Endnotes

¹ 134 F. Supp. 829 (D WD Pa, 2 Aug 1955).

² Federal Regulation of Tobacco, available at www.americanheart.org/presenter.jhtml?identifier=11223.

³ Robert A. Kagan & William P. Nelson, “The Politics of Tobacco Regulation in the United States,” available at http://www.igs.berkeley.edu/research_programs/hist_papers/tobacco.pdf.

⁴ Summary of the Attorney Generals Master Settlement Agreement, Joy Johnson Wilson, Director, AFI Health Committee, March 1999, for the National Conference of State Legislatures, available at <http://www.ncsl.org/statefed/tmsasumm.htm>.

⁵ *Id.*

⁶ *Id.*

⁷ Greg Winter, “State Officials are Faulted on Anti-Tobacco Programs,” *New York Times*, Jan. 11, 2002 (stating that while most states have used their settlement money to “offset Medicaid expenses, support children’s programs or improve education,” the payments “have also gone to run boot camps for juvenile offenders in Alabama, build levees in North Dakota and provide tax cuts in Illinois and Connecticut”).

⁸ The 19 states include Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Maine, Maryland (effective February 1, 2008), Massachusetts, Minnesota, Montana (extends to bars Jan 1, 2009), New Jersey, New Mexico, New York, Ohio, Rhode Island, Utah (extends to bars Jan 1, 2009), Vermont, Washington. Source: Michael Strande, Managing Attorney, Legal Resource Center for Tobacco Regulation, Litigation and Advocacy at the University of Maryland School of Law. See also State Legislated Action on Tobacco Issues (SLATI) Overview, American Lung Association, available at <http://slati.lungusa.org/StateLegislateAction.asp>.

⁹ See SLATI, *supra* note 8.

¹⁰ *Id.*

¹¹ “An International treaty for tobacco control,” World Health Organization, 12 August 2003 available at www.who.int/features/2003/08/en/print.html.

¹² Jeff Collin, “Tobacco Politics,” 47 *Development* 91, 92 (2004).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ See S. 625 introduced by U.S. Senators Edward M. Kennedy (D-MA) and John Cornyn (R-TX) on February 15, 2007 and H.R. 1108, introduced by U.S. Representatives Henry A. Waxman (D-CA) and Tom Davis (R-VA) on the same day.

¹⁶ *Id.*

¹⁷ Poll reported at <http://www.jointogether.org/news/headlines/inthenews/2007/poll-finds-support-for-fda.html>.

¹⁸ *Id.*

Center for Tobacco Regulation

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centers—the Secondhand Smoke Technical Assistance Resource Center (Colorado) and the Tobacco Public Policy Center (Ohio).

The TCLC is funded in part by a grant from the Robert Wood Johnson Foundation and the American Cancer Society. The TCLC's coordinating office is located at the William Mitchell College of Law in St. Paul, Minnesota and is staffed by Doug Blanke, the Executive Director, and three attorneys. Drawing on the expertise of these legal centers and others, the TCLC provides assistance to support the creation of new legal programs and to help communities and states with legal needs and technical assistance services such as legislative drafting, legal research, legal analysis and strategy, training and presentations, preparation of friend-of-the-court briefs, and litigation support.

TCLC also publishes synopses of tobacco related legislation and court cases. In June 2005, TCLC published "Secondhand Smoke and the Family Courts: The Role of Smoke Exposure in Custody and Visitation Decisions." The paper, written by Professor Dachille and Tobacco Center Research Fellow and 2004 School of Law graduate Kristine Callahan, has led to many inquiries from individuals dealing with parental smoking in custody and visitation cases.

In addition, the TCLC has published written law synopses on such topics as secondhand smoke and casinos,¹ legal options for condominium owners exposed to secondhand smoke,² the problems associated with internet cigarette retailers,³ and an overview of the ways in which local land use regulations, such as zoning laws, might be used to control the location and operation of tobacco retailers.⁴

The flavored tobacco products issue is a topic currently under scrutiny by the TCLC and the subject of a 2006 law synopsis entitled "Protecting Maryland Youth from Candy-Flavored Cigarettes and Smokeless Tobacco Products" by Professor Dachille. In that synopsis, Dachille urged Maryland to pass a bill that would prohibit the sale of candy-flavored cigarettes and smokeless tobacco

products. She argues that states must take the initiative to ban candy-flavored tobacco products, which are disguised as sweet-flavored treats that serve to entice and initiate youth because they provide an attractive alternative to the offensive and strong taste of the average tobacco product. Dachille noted that, although children and adolescents are already prohibited from purchasing tobacco products, the system of age-verification and enforcement is faulty and thus leaves plenty of room for young people to fall between the cracks and purchase these products illegally.

Tobacco Center: Non-Legislative Projects

The most common complaint the Center receives is from individuals living in multi-unit dwellings – apartments, condominiums or townhouses – who are bothered by tobacco smoke drifting into their unit from an adjacent unit. For some complainants, the smokedrift is so pervasive as to render some rooms uninhabitable; for others, the smokedrift is a nuisance that carries health concerns. The Center also fields inquiries from landlords and management companies considering adoption of a smokefree building policy; similar inquiries come from condominium boards.

This summer the Center will launch an effort to educate landlords, tenants, condominium owners, and condominium boards about each group's legal rights and responsibilities regarding smokedrift in multi-unit housing. The campaign will include a comprehensive website, an educational brochure for tenants and another for landlords, model policies for management companies and condominium boards, and a listing of available smokefree housing.

The Center is also working with the Maryland Park Service to recommend to the Parks Commission a policy concerning tobacco use on all state park property. While some local jurisdictions in Maryland

have adopted smokefree policies for their recreation and park properties and some states have done so for state park property, Maryland does not have a tobacco use

policy for state parks. In light of the environmental, fire safety, and health concerns associated with tobacco use in parks, Center staff believe the state should adopt a comprehensive policy. Center Director Kathleen Dachille recently made a presentation to the

State Parks Commission on this issue.

Finally, the Center is preparing a policy paper, along with recommendations for local governments, on dealing with the health implications of hookah bars. These establishments offer patrons the opportunity to purchase, and smoke in a water pipe, flavored tobacco known as shisha. Most hookah establishments also serve alcohol or food and so will likely be subject to the clean indoor air restrictions that go into effect on February 1, 2008. It is possible, however, for a hookah establishment to meet the tobaccoist exception in that law or to apply successfully for a waiver. Hookah smoking presents health risks in addition to those associated with smoking and secondhand smoke, including the transmission of communicable diseases from sharing of a stem or pipe. The Center plans to offer local health departments and legislatures regulatory or legislative proposals that are designed to diminish the health risks associated with hookah use.

Tobacco Center: Litigation

Another critical function of the Tobacco Center is providing legal assistance to lawyers representing local governments. This assistance can take several forms, including training in statistics and epidemiology essential to making persuasive arguments about causation of illness or injury from tobacco products, mooted oral arguments for attorneys preparing to argue tobacco cases, and drafting briefs or arranging for amicus briefs for attorneys representing



local governments or community coalitions.

The Center also monitors and provides high level litigation support to state governments involved in tobacco litigation. Recently, Center Director Dachille was appointed as a Special Assistant Attorney General in Maryland to work in support of the Vermont Attorney General's case against R.J. Reynolds for the marketing of the Eclipse cigarette. Eclipse has been marketed as a cigarette posing less risk of lung cancer and emphysema and as emitting significantly less secondhand smoke than traditional cigarettes. The Vermont Attorney General sued Reynolds alleging that the marketing of Eclipse is deceptive and in violation of the Vermont Consumer Fraud Statute and the Master Settlement Agreement. More than a dozen states are lending litigation support; the Center has joined that support team through Dachille's appointment and uses invaluable and plentiful student research skills to support the team.

Conferences

The Center has sponsored a number of conferences, workshops and symposia in the five years since its inception, including noteworthy conferences on new tobacco products, fire-safe cigarettes and youth sales enforcement. On April 20, the Center sponsored a national one-day conference on so-called "reduced harm" or "reduced-exposure" tobacco products. Participants in this conference tackled the question of how the public health community should respond to these products and the legal issues surrounding their marketing and use. (See article, p. 5.)

Endnotes

¹ Secondhand Smoke and Casinos, Micah Berman & Caris Post, available at <http://tclconline.org/resourcesTCLC.html>.

² Legal Options for Condominium Owners Exposed to Secondhand Smoke, Susan Schoenmarklin, available at <http://tclconline.org/resourcesTCLC.html>.

³ Public Health Policy for Internet Cigarette Retailers. Christopher Banthin, available at <http://tclconline.org/resourcesTCLC.html>.

⁴ Local Land Use Regulation for the Location and Operation of Tobacco Retailers, Randolph Kline, available at <http://tclconline.org/resourcesTCLC.html>.

Faculty at the Forefront

Cont. from p. 10

hospitals in a state. With both surveillance screening and mandatory reporting of nosocomial infections individual test results and aggregate data will be created that could be used against a hospital in a civil law suit based on damages resulting from a nosocomial infection.

To address these legal issues, Professor Diane Hoffmann was invited to speak in April at the annual meeting of the Society for Healthcare Epidemiology of America (SHEA). In her talk, "Law & Order: the Changing Legal Landscape Around Healthcare Associated Infections," Hoffmann discussed the success of nosocomial infection lawsuits in the nation's courts, defenses to such actions, and whether state and federal laws confer any statutory protection over the use of information generated by mandatory reporting or surveillance screening in civil lawsuits. She also addressed the likelihood that the standard of care with regard to the prevention of nosocomial infections will rise given evidence that adoption of certain procedures can significantly reduce the incidence of these infections. Hoffmann concluded that mandatory reporting statutes and pre-admission screening for nosocomial diseases may represent a risk to hospitals in the civil litigation arena but, on an optimistic note, noted that such reporting and screening is also likely to result in fewer cases of nosocomial infection, and therefore, fewer lawsuits. Hoffmann will be discussing this issue at the upcoming Health Law Professors Conference at Boston University in June.

Endnotes

¹ Hidron, Alice, *et al.*, Clinical Infectious Diseases 2005; 41: 167-9.

² Davis, K.A., *et al.*, Clinical Infectious Diseases 2004; 39: 776-82.

³ MRSA: An Action Network Briefing, BBC. Available at <http://www.bbc.co.uk/dna/actionnetwork/A2836550>.

Faculty & Students in Africa

Cont. from p. 11

first national legal conference on the issue. Rothenberg's research was later incorporated into both New York state policy and CDC recommendations on HIV/AIDS partner notification.

Rothenberg spoke to the University of Capetown audience about the three analytical principles that emerged from her research regarding women with HIV/AIDS: interdependence, gender relevance and shifting paradigms. She explained that her research led her to understand that public health issues cannot be studied in isolation from each other; that gender does matter when making public health policy; and, finally, that policy makers need to understand and adapt to shifting paradigms if their work is to be effective. One example of a shifting paradigm that Rothenberg discussed was the change in the United States from perceiving HIV/AIDS as a death sentence to a chronic disease and the policy implications of this shift in perception. She urged the South African audience to employ these analytical principles to their future research on the ways in which HIV/AIDS is both a trigger and result of domestic violence.

*Students pictured were externing in South Africa for the semester.

Students Attend Conference

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views of five Framework Convention Alliance members by reading prepared statements. Alva spoke on behalf of Action on Smoking & Health (UK) and Lauren on behalf of the University of California at San Francisco. According to Lauren, her experiences in Brazil have given her “a greater understanding of the issues associated with tobacco cultivation and the inner workings of implementing a global public health treaty.” Bostic commented that, in addition to being an incredibly enriching experience for students in the short term, including students in high-level meetings trains them to enter the tobacco control community upon graduation from law school.

Alum Working at W.H.O.

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Recently, Vestal worked with the Director of the Law & Health Care Program, Diane Hoffmann, and Program Coordinator, Virginia Rowthorn, to set up an externship program in the TFI for University of Maryland law school students. Under this new externship placement, students will work with Vestal on various legal and regulatory issues relating to international tobacco control. Although other L&HCP students have had externships at WHO in the office of the General Counsel, the first student to work as an extern with the Tobacco Free Initiative left for Geneva this month. Vestal says she is very grateful to “the many people who have opened doors for me,” and this has made her committed to opening doors to qualified and motivated University of Maryland law students.

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